K003520

DEC 13 2000

11 Safety and Efficacy - Premarket Notification 510(k) Summary

510(k) Summary as required per 807.92.

11.1 Submitter Details

Nexan Ltd
The Quorum
Barnwell Road
Cambridge
CB5 8RE
United Kingdom

Contact: Dr J. D. Place – Operations Director
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Date of submission: 13th November 2000

11.2 Device Name and Classification

11.2.1 Device name

Nx-300 system

11.2.2 Device Common Name

Ambulatory Patient Monitor

11.2.3 Classification, product code

Class: II
Product Code: MWJ CFR:870.2800
ELECTROCARDIOGRAPH, AMBULATORY (WITHOUT ANALYSIS)

11.3 Predicate Device Information

The device has been compared to the original cleared device:

Company	Device	510(k)
Nexan Ltd	Nexystem NEX 100 Patient Home Monitoring System	K993643

11.4 Device Description

The Nx-300 system is a non-invasive ambulatory patient monitoring system for recording multiple physiological parameters from patients who may be located at home or in an alternate care setting. The Nx-300 system continuously gathers physiological data from a sensor band (Nexi) attached to the patient and transmits the data wirelessly (Nexi-Clip)to a Signal Transfer Unit (PDA) where the data are recorded and stored. The data is transferred to a Base Station by docking the PDA in the BSU. Additionally, the Base Station Unit has interfaces for auxiliary sensors – spirometer and blood pressure monitor – for recording point in time lung function and blood pressure measurements. A Call Discriminator Unit within the BSU enables incoming telephone calls to be correctly routed to either the BSU or a telephone handset.

The data are transmitted for display, monitoring and storage on a computer (Telemonitoring Station TMS running the Nexoft application software) at a distant location (Telemonitoring Centre). This data transfer is under the control of the Health Care Professional (HCP) at the TMS. Data may be transferred in real time to enable the HCP to check on the quality of the physiological data being recorded and/or the status of the patient. Normally data is transferred at a scheduled time after the end of a patient data recording session. Once transferred to the TMS the data can subsequently be displayed for analysis by the HCP. The Nx-300 system enables the HCP to print reports of raw data

11.5 Intended Use

The Nx-300 system is an ambulatory patient monitoring system intended for use in the home or alternate care settings. The device stores and transmits ECG data, respiration data, systolic and diastolic blood pressure (non-invasive), and PEF and FEV1.

11.6 Non-clinical performance data for equivalence

11.6.1 ANSI/AAMI EC12

The Nexisensor Compliance has been tested and found to comply with ANSI/AAMI EC12 Disposable ECG Electrodes.

11.6.2 ANSI/AAMI EC38

Compliance testing of the Nx-300 system to ANSI/AAMI EC38 Ambulatory Electrocardiographs has been conducted.
The report concludes that the Nx-300 system is a Type I ambulatory electrocardiograph and is compliant with ANSI/AAMI EC38.

11.7 Clinical performance data for equivalence

Not applicable

11.8 Predicate Device Comparison

The comparison of intended use and technological features of the Nx-300 system with the cleared device taken together with the validation results, performance tests and other information in this submission indicate the Nx-300 system is substantially equivalent in safety, effectiveness and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2000

Dr. J. D. Place
Operations Director
Nexan, Ltd.
The Quorum
Barnwell Road
Cambridge CB5 8RE United Kingdom

Re: K003520
Trade Name: Nexan System, Model NX-300
Regulatory Class: II (two)
Product Code: 74 MWJ
Dated: November 13, 2000
Received: November 15, 2000

Dear Dr. Place:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification

submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4346. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Health
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

12 Indications for Use Statement.

510(k) Number (if known): K003520

Device Name: Nx-300 Ambulatory Patient Monitor

Indications For Use:

The Nx-300 system is an ambulatory patient monitoring system intended for use in the home or alternate care settings. It consists of a patient worn sensor (Nexi), Personal Data Assistant, communications module (Base Station), and a Telemonitoring Station computer based display and storage system (TMS) located at the health care professional's facility. The device stores and transmits ECG data, respiration data, systolic and diastolic blood pressure (non-invasive), and PEF and FEV1.

Federal Law (US) Restricts this device to sale by or on the order of a physician

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003520

Prescription use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)